DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive S.E.
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

M3884

COPY

June 2, 2000

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 00-47

Roger A. Lobry, Owner
Lyle's Seafoods
23223 Sandridge Road
Ocean Park, Washington 98640

WARNING LETTER

Dear Mr. Lobry:

We inspected your firm located at 23223 Sandridge Road, Ocean Park, Washington, on December 6-8, 1999, and found that you have serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 113 – Thermally Processed Low–Acid Foods Packaged in Hermetically Sealed Containers. A FDA 483 form (copy enclosed) listing the deviations was presented to Kimberly S. Lobry, Manager, at the conclusion of the inspection. These deviations cause your canned smoked sturgeon to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the Low-Acid Foods regulations through links in FDA's homepage at www.fda.gov.

The deviations were as follows:

1. Your firm's vertical retort #1 did not have a bleeder installed in that portion of the retort opposite the steam inlet in order to comply with 21 CFR 113.40(a)(8). Your vertical retort #1 has a top steam inlet, therefore, 21 CFR 113.40(a)(8) requires the bleeder to be installed in the bottom of the retort. A bleeder is required in the bottom of the retort to remove condensate

2. Your firm's vertical retort #1 installation does not have the specifications outlined in 21 CFR 113.40(a)(12)(ii). Your firm did not have the heat distribution data required by 21 CFR 113.40(a)(12)(iii) demonstrating that adequate venting of air is accomplished since the installation deviates from the specifications.

3. Your firm failed to mark each container of canned smoked sturgeon with an identifying code permanently visible to the naked eye [(21 CFR 113.60(c)]. Specifically, for the number 9 in the code "112389 91001", the matrix die appeared to be the number 6, which did not match the 9 of the punch die, resulting in an illegible embossing of "9" in the code.

4. Your firm did not provide means to prevent unauthorized changes in adjustment to the temperature recording device [(21 CFR 114.40(a)(2)].

The above LACF violations are not meant to be an all-inclusive list of deficiencies in your plant. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA, including the Seafood HACCP regulations and the Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food regulations in 21 CFR 110. We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product and/or require that your firm obtain a temporary emergency permit in accordance with 21 CFR 108.5. Pertinent sections of the Act and regulations are enclosed for your review.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Elrand, Compliance Officer, 22201 23rd Drive SE; Bothell, Washington 98021-4421. If you have questions regarding any issue in this letter, please contact Lisa Elrand at (425) 483-4913.

Sincerely,

Charles M. Breen
District Director

Enclosures:
Form FDA 483
21 CFR Part 113
21 CFR Part 123
Section 402 of the Federal Food, Drug, and Cosmetic Act

cc: with disclosure statement
WSDA